K063135
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North American Industrial manufacturing company
4120 South Creek Road
Chattanooga, TN 37406

FEB 5 2007

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# 510(k) Summary

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| Submitter's Information: | Julie Creasman, Regulatory Affairs Manager<br>NAImco, Inc.<br>4120 South Creek Road<br>Chattanooga, TN 37406<br>Phone: 888-549-4945<br>Fax: 423-648-7735 |
| Date of Preparation: | February 1, 2007 |
| Proprietary Name: | Sonic-Stim |
| Common Name: | Ultrasound and Powered Muscle Stimulator |
| Classification Name: | Ultrasound and Powered Muscle Stimulator (per 21 CFR 890.5860 and 21 CFR 882.5890) |
| Predicate Device: | K031077 (Chattanooga Group Vectra GENiSYS)<br>K010749 (Biomedical Life Science, QUADSTAR II) |
| Description of Device: | Ultrasound and Muscle Stimulator. Transcutaneous electrical nerve stimulator for pain relief, Powered muscle stimulator. Available as 2 channel stimulator, 4 channel stimulator, ultrasound, 2 channel stimulator with ultrasound, and 4 channel stimulator with ultrasound.<br><br>Units are supplied with electrodes listed in 510(K) K050469, typically 2 x 2 inch.<br><br>Units are supplied with a bottle of ultrasound coupling gel listed in 510(K) K012522, or similar gels already in the market. |
| Intended Use: ✓ | **For Russian, and High Volt**<br>• Relaxation of muscle spasms<br>• Prevention or retardation of disuse atrophy<br>• Increase local blood circulation<br>• Muscle re-education<br>• Maintaining or increasing range of motion |

- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

✓ **For interferential and premodulated interferential**

- Symptomatic relief of chronic, intractable pain
- Management of pain associated with post-traumatic or post-operative conditions

✓ **For Ultrasound**

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:

- Pain Relief
- Reduction of muscle spasms
- Joint contractures

✓ **For TENS and EMS**

- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment in the management of post surgical and post traumatic acute pain condition

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| Technological Comparison: | Summary of the technological characteristics compare to the predicate devices. |
| Labeling Comparison: | Labeling of the device compares to that of predicate devices. |
| Non-clinical Testing: | Not Applicable |
| Clinical Testing: | Not Applicable |
| Conclusions: | As provided in the Comparison and Standards sections, the Sonic-Stim device models have similar characteristics and are equivalent to models of the VECTRA GENiSYS and the QUADSTAR II. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

North American
Industrial Manufacturing Company
% Julie Creasman
Regulatory Affairs Manager
4120 South Creek Road
Chattanooga, TN 37406

FEB 5 2007

Re: K063135
Trade/Device Name: Sonic-Stim
Regulation Number: 21 CFR 890.5860, 21 CFR 882.5890
Regulation Name: Ultrasound and muscle stimulator
Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: IMG, GZJ, IPF, GZI.
Dated: December 19, 2006
Received: December 28, 2006

Dear Ms. Creasman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NAmco
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# Indications for Use

K063135

Device Name: Sonic-Stim

**For Russian, and High Volt**

- Relaxation of muscle spasms
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- Increase local blood circulation
- Muscle re-education
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- Adjunctive treatment in the management of post surgical and post traumatic acute pain condition

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063136